

### § 158.3

### 40 CFR Ch. I (7–1–10 Edition)

(2) *Biochemical pesticides*. Subparts A, B and U apply to biochemical pesticides.

(3) *Microbial pesticides*. Subparts A, B and V apply to microbial pesticides.

(4) *Antimicrobial pesticides*. [Reserved]

#### § 158.3 Definitions.

All terms defined in sec. 2 of the Federal Insecticide, Fungicide, and Rodenticide Act apply to this part and are used with the meaning given in the Act. Applicable terms from the Federal Food, Drug, and Cosmetic Act also apply to this part. Individual subparts may contain definitions that pertain solely to that subpart. The following additional terms apply to this part:

*Applicant* means any person or entity, including for the purposes of this part a registrant, who submits, or is required to submit, to the Agency any application, petition, or submission intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide. Such submissions may include, but are not limited to, the following:

(1) An application for registration or amended registration of a pesticide product under FIFRA sec. 3 or 24.

(2) A submission of data required in conjunction with reregistration of a currently registered product under FIFRA sec. 4.

(3) An application for an experimental use permit under FIFRA sec. 5.

(4) A submission of data in response to a notice issued by EPA under FIFRA sec. 3(c)(2)(B).

(5) A petition to establish or modify a tolerance or an exemption from the requirement of a tolerance for a pesticide chemical residue under FFDCA sec. 408.

*Registration* includes a new registration, amended registration and reregistration, unless stated otherwise.

#### § 158.5 Applicability.

(a) The requirements of this part apply to the following submissions:

(1) An application for new or amended registration under FIFRA sec. 3 or 24.

(2) An application for experimental use permit under FIFRA sec. 5.

(3) A submission of data or information to support the continuation of a registration under FIFRA sec. 3, 4, or 24.

(4) A petition to establish, modify or revoke a tolerance or exemption from a tolerance under FFDCA sec. 408.

(b) The information specified in this part must be furnished with each submission described in paragraph (a) of this section if it has not been submitted previously, or if any previous submission is not accurate or complete.

#### § 158.30 Flexibility.

(a) FIFRA provides EPA flexibility to require, or not require, data and information for the purposes of making regulatory judgments for pesticide products. EPA has the authority to establish or modify data needs for individual pesticide chemicals. The actual data required may be modified on an individual basis to fully characterize the use and properties, characteristics, or effects of specific pesticide products under review. The Agency encourages each applicant to consult with EPA to discuss the data requirements particular to its product prior to and during the registration process.

(b) The Agency cautions applicants that the data routinely required in this part may not be sufficient to permit EPA to evaluate the potential of the product to cause unreasonable adverse effects to man or the environment. EPA may require the submission of additional data or information beyond that specified in this part if such data or information are needed to appropriately evaluate a pesticide product.

(c) This part will be updated as needed to reflect evolving program needs and advances in science.

#### § 158.32 Format of data submissions.

(a) *General*. (1) All data submitted under this part must be formatted in accordance with this section.

(2) The requirements of this section do not apply to administrative materials accompanying a data submission, including forms, labeling, and correspondence.